

**Wichita State University Institutional Review Board
for the Protection of Human Subjects (IRB)**

APPLICATION FOR APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS

Please use a typewriter to complete this form.

Name of Principal

Investigator(s): _____
(For a student project, Principal Investigator **must** be a WSU faculty member; student is listed as Co-Investigator.)

Departmental/Program

Affiliation: _____ Campus Box: _____ Phone: _____

Name(s) of Co-

Investigator(s): _____

Co-Investigator(s) is/are: ☐ Faculty Member ☐ Graduate Student ☐ Undergraduate Student

Type of Project: ☐ Class Project ☐ Capstone Project ☐ Thesis or Dissertation

☐ Funded Research ☐ Unfunded Research

If student project, address of student: _____

Title of Project/Proposal: _____

Expected Completion Date: _____ Funding Agency (if applicable): _____

Please attach additional sheets, if necessary, with numbers of responses corresponding to those listed below.

1. Describe the research in non-technical language:

2. Describe the benefits of the research to the human subjects, if any, and of the benefits to human or scientific knowledge:

3. Describe the subjects, how the subjects are to be selected, how many are to be used, and indicate explicitly whether any are minors (under age 18 per Kansas law) or otherwise members of "vulnerable" populations, including, but not limited to, pregnant women, prisoners, psychiatric patients, etc.
4. Describe each procedure step-by-step, including the frequency, duration, and location of each procedure.
5. Describe any risks or discomforts (physical, psychological, or social) and how they will be minimized.
6. Describe how the subject's personal privacy is to be protected and confidentiality of information guaranteed (e.g. disposition of questionnaires, interview notes, recorded audio or videotapes, etc.).
7. Describe the informed consent process and attach a copy of all consent and/or assent documents. These documents **must** be retained for three years beyond completion of the study. Any waiver of written informed consent must be justified.
8. Attach all supporting material, including, but not limited to, questionnaire or survey forms and letters of approval from cooperating institutions.

The Principal Investigator agrees to abide by the federal regulations for the protection of human subjects and to retain consent forms for a minimum of three (3) years beyond the completion of the study. If the data collection or testing of subjects is to be performed by student assistants, the Principal Investigator will assume full responsibility for supervising the students to ensure that human subjects are adequately protected.

Signature of Principal Investigator

Date

Signature of Co-investigator (for student project)

Date

NOTE: THE CONSENT FORM MUST BE PLACED ON WSU DEPARTMENTAL LETTERHEAD

MODEL CONSENT FORM

PURPOSE: You are invited to participate in a study of (STATE WHAT IS BEING STUDIED). I/we hope to learn (STATE WHAT THE STUDY IS DESIGNED TO DISCOVER OR ESTABLISH).

PARTICIPANT SELECTION: You were selected as a possible participant in this study because (STATE WHY AND HOW SUBJECT WAS SELECTED; IDENTIFY THE POPULATION AND NUMBER OF SUBJECTS).

EXPLANATION OF PROCEDURES: If you decide to participate, you will (DESCRIBE THE PROCEDURES TO BE FOLLOWED, INCLUDING THEIR PURPOSES, HOW LONG THEY WILL TAKE, AND THEIR FREQUENCY).

DISCOMFORT/RISKS: (DESCRIBE ANY RISKS, DISCOMFORTS AND INCONVENIENCES THAT MAY REASONABLY BE EXPECTED).

BENEFITS: (DESCRIBE ANY BENEFITS TO SUBJECTS OR SOCIETY THAT MAY REASONABLY BE EXPECTED).

CONFIDENTIALITY: Any information obtained in this study in which you can be identified will remain confidential and will be disclosed only with your permission. (IF YOU WILL BE RELEASING INFORMATION TO ANYONE FOR ANY REASON, YOU MUST STATE THE PERSONS OR AGENCIES TO WHOM THE INFORMATION WILL BE GIVEN, THE NATURE OF THE INFORMATION TO BE GIVEN, AND THE PURPOSE OF THE DISCLOSURE).

COMPENSATION OR TREATMENT: IF RESEARCH-RELATED INJURY (PHYSICAL, PSYCHOLOGICAL, SOCIAL, FINANCIAL, OR OTHERWISE) IS POSSIBLE IN RESEARCH THAT IS MORE THAN MINIMAL RISK AND/OR RESEARCH THAT INVOLVES PHYSICAL ACTIVITY, YOU MUST INCLUDE THE FOLLOWING: Wichita State University does not provide medical treatment or other forms of reimbursement to persons injured as a result of or in connection with participation in research activities conducted by Wichita State University or its faculty, staff, or students. If you believe that you have been injured as a result of participating in the research covered by this consent form, you can contact the Office of Research Administration, Wichita State University, Wichita, KS 67260-0007, telephone (316) 978-3285.

REFUSAL/WITHDRAWAL: Participation in this study is entirely voluntary. Your decision whether or not to participate will not affect your future relations with Wichita State University and/or (INCLUDE NAME OF ANY OTHER INSTITUTION OR AGENCY INVOLVED). If you agree to participate in this study, you are free to withdraw from the study at any time without penalty.

CONTACT: If you have any questions about this research, you can contact me at: (NAME, ADDRESS AND PHONE. *NOTE: For student project, include contact information for student AND faculty member*). If you have questions pertaining to your rights as a research subject, or about research-related injury, you can contact the Office of Research Administration at Wichita State University, Wichita, KS 67260-0007, telephone (316) 978-3285.

You are under no obligation to participate in this study. Your signature indicates that you have read the information provided above and have voluntarily decided to participate.

You will be given a copy of this consent form to keep.

Signature of Subject

Date

Signature of Parent or Legal Guardian
(omit for subjects consenting for themselves)

Date

Witness Signature

Date

Form A

NOTE: THE CONSENT FORM MUST BE PLACED ON WSU DEPARTMENTAL LETTERHEAD

Obtaining Informed Assent from Children or Minors

Parents, legal guardians or a legally authorized official **must** sign consent forms permitting children or minors to participate in research projects. In addition, children and minors are required to sign an **ASSENT FORM**. Language must be simplified as appropriate for the age group used as subjects. The following are two samples of an Assent Form:

MODEL CHILD ASSENT FORM

I have been told that my parents (mom or dad) have said it's okay (or, have given permission) for me to participate, if I want to, in a project about _____.

I know that I can stop at any time I want to and it will be okay if I want to stop.

Name

Date

OR

I have been informed that my parent(s) have given permission for me to participate, if I want to, in a study concerning _____. My participation in this project is voluntary and I have been told that I may stop my participation in this study at any time. If I choose not to participate, it will not affect my grade (or treatment/care [select whichever applies]) in any way.

Name

Date

Form B

NOTE: THE CONSENT FORM MUST BE PLACED ON WSU DEPARTMENTAL LETTERHEAD

MODEL COVER LETTER FOR MAIL-OUT QUESTIONNAIRE/SURVEY

PURPOSE: You are invited to participate in a study of (STATE WHAT IS BEING STUDIED). I/we hope to learn (STATE WHAT THE STUDY IS DESIGNED TO DISCOVER OR ESTABLISH).

PARTICIPANT SELECTION: You were selected as a possible participant in this study because (STATE WHY AND HOW SUBJECT WAS SELECTED; IDENTIFY THE POPULATION AND NUMBER OF SUBJECTS).

EXPLANATION OF PROCEDURES: If you decide to participate, you will (DESCRIBE THE PROCEDURES TO BE FOLLOWED, INCLUDING THEIR PURPOSES, HOW LONG THEY WILL TAKE, AND THEIR FREQUENCY).

DISCOMFORT/RISKS: (DESCRIBE ANY RISKS, DISCOMFORTS AND INCONVENIENCES THAT MAY REASONABLY BE EXPECTED).

BENEFITS: (DESCRIBE ANY BENEFITS TO SUBJECTS OR SOCIETY THAT MAY REASONABLY BE EXPECTED).

CONFIDENTIALITY: Any information obtained in this study in which you can be identified will remain confidential and will be disclosed only with your permission. (IF YOU WILL BE RELEASING INFORMATION TO ANYONE FOR ANY REASON, YOU MUST STATE THE PERSONS OR AGENCIES TO WHOM THE INFORMATION WILL BE GIVEN, THE NATURE OF THE INFORMATION TO BE GIVEN, AND THE PURPOSE OF THE DISCLOSURE).

REFUSAL/WITHDRAWAL: Participation in this study is entirely voluntary. Your decision whether or not to participate will not affect your future relations with Wichita State University and/or (INCLUDE NAME OF ANY OTHER INSTITUTION OR AGENCY INVOLVED). If you agree to participate in this study, you are free to withdraw from the study at any time without penalty.

CONTACT: If you have any questions about this research, you can contact me at: (NAME, ADDRESS AND PHONE. *NOTE: For student project, include contact information for student AND faculty member*). If you have questions pertaining to your rights as a research subject, you can contact the Office of Research Administration at Wichita State University, Wichita, KS 67260-0007, telephone (316) 978-3285.

You are under no obligation to participate in the study. Your completing and returning this questionnaire will be taken as evidence of your willingness to participate and your consent to have the information used for the purposes of the study.

You may keep this cover letter and explanation about the nature of your participation in this study and the handling of the information you supply.

Sincerely,

Name and signature of investigator Date

Form C